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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/804,408

03/12/2001

Mathew F. Ogle

1416.20US01

1108

27367

7590

06/01/2006

WESTMAN CHAMPLIN & KELLY, P.A.

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EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/804,408

Applicant(s)

OGLE ET AL

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-28 and 34-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-28 and 34-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/10/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/24/06 has been entered.

An amendment filed 3/24/06 amended claims 1, 16, 34 and 36.

Claims examined on the merits are 1-9, 11-28 and 34-43, which are all claims in the application.

The documents listed on form 1449 of 2/10/03 have been lined through since the documents are also listed on form 1449 of 9/26/03.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 11-28 and 34-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey

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to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Support is not found in the specification for reciting "the bridges are not glutaraldehyde" in claims 1 and 16, and "the bridge molecules are not glutaraldehyde" in claims 34 and 36. The specification nowhere sets forth that the bridges are not glutaraldehyde. While the specification discloses bridge substances that are not glutaraaldehyde, other compounds having the cross-linking function of glutaraldehyde are also not included with the specific bridges recited. There is no basis in the specification for only glutaraldehyde being excluded as a bridge because it is not included in the specific bridge materials recited in the specification (pages 19 and 20). To exclude glutaraldehyde as a bridge, it is suggested the claims be amended to recite a Markush group of the specific bridge compounds recited in the specification.

Claim Rejections - 35 USC § 103

Claims 1-9, 11-28 and 34-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle et al (5,958,669) in view of Yang et al (5,935,168).

The claims are drawn to tissue containing linkers bonded to tissue and bridge molecules (excluding glutaraldehyde) bonded between two or more of the linkers, to a method of crosslinking tissue to prepare the tissue having linkers and bridge molecules, to tissue containing modified sites having bridge molecules bonded to two or more of the modified sites, and to a method of crosslinking tissue to

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prepare the tissue having modified sites and bridge molecules. In all these embodiments, functional groups of the bridges are required to be generally non-reactive with other bridges.

Ogle et al disclose crosslinking tissue to fix tissue by reacting
5 the tissue with glutaraldehyde.

Yang et al disclose crosslinking tissue with glutaraldehyde, and then reacting with a diamine followed by reacting with additional glutaraldehyde (col 1, line 43 and claims 8-10).

After reacting with glutaraldehyde as disclosed by Ogle et al, it
10 would have been obvious to react with a diamine and then with additional glutaraldehyde as suggested by Yang et al. This will result in the diamine being a linker and the glutaraldehyde being bridge. Additionally, after initially crosslinking with glutaraldehyde some free aldehyde groups will remain that will react
15 with the diamine and result in the glutaraldehyde being a linker and the diamine being a bridge. In this embodiment, glutaraldehyde is not the bridge. The aldehyde groups of glutaraldehyde are generally non-reactive with other aldehyde groups of another glutaraldehyde under certain conditions disclosed by Ogle et al that control self-
20 polymerizing. The amine groups of a diamine will not react with amine groups of another diamine. This will result in a bridge not reacting with another bridge.

Response to Arguments

Applicant's arguments filed 3/12/06 have been fully considered
25 but they are not persuasive.

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Applicants urge that free aldehyde groups resulting from the glutaraldehyde used by Yang et al is contrary to the disclosure of Yang et al. However, the rejection is not based on Yang et al alone, but also on Ogle et al. Ogle et al disclose (col 6, lines 52-55) that

5 tissue has reduced susceptibility to calcification due to unreacted aldehyde groups, and suggests determining the quantity of unreacted aldehyde groups to determine susceptibility to calcification.

Therefore, it is clear that reacting the glutaraldehyde cross-linked tissue of Ogle et al with a diamine as suggested by Yang et al will

10 result in the diamine forming cross-links between the free aldehyde groups. When free aldehyde groups are present, a diamine will react with both activated carboxyl groups and the free aldehyde groups. The present claims do not exclude the tissue containing activated carboxyl groups, and the bridges reacting with groups on the tissue in addition

15 to reacting with the linkers. The diamine reacting with free aldehyde groups will reduce calcification as desired by Yang et al, as well as Ogle et al, since Ogle et al disclose that free aldehyde groups result in calcification. Thus, it would have been apparent that reacting free aldehyde groups in Ogle et al with a diamine can reduce

20 calcification without additional reacting with glutaraldehyde as in Yang et al.

Conclusion

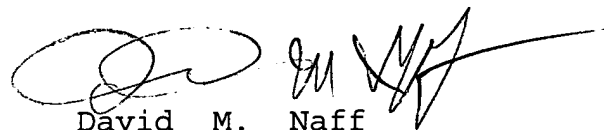
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff

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whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

DMN
5/30/06